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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,639	01/22/2004	Dmitry E. Protsenko	UCI.PAU.33	5303

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EXAMINER
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VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/762,639

Applicant(s)

PROTSENKO ET AL.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 1-34 and 63-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The action is non-final. Claims 1-34 and 63-73 are withdrawn. Claims 35-62 are examined below. Claim 35 is the lone independent claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 35-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Balbierz (6,770,070).

*Note: a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.*

Balbierz discloses:

35. An apparatus of electroforming tissue comprising:

means for creating stress in the tissue (see electrode 18 in figures 9 and distal end of device 16 in figures 5); and

means for causing a current to flow in the tissue (power source 20 in figure 7 and electrode 18 in figures 9) while the created stress is present to change shape of the tissue or material parameters of the tissue (inherent).

36. The apparatus of claim 35 where the means for causing a current to flow in the tissue comprises means for causing a direct current of a predetermined ("preset", col. 24:46) polarity (monopolar, bipolar changes in col. 24:46-53) to flow (power source 20) in the tissue to mediate the tissue. This claim includes intended use language.

37. The apparatus of claim 35 where the means for creating stress in the tissue comprises means for mechanically applying force (see distal end of device 16 in figures 9) to the tissue to create external stresses applied to the tissue.

38. The apparatus of claim 35 where the means for creating stress in the tissue comprises means for changing material parameters (tissue puncturing edges - see distal end of device 16 in figures 9) of the tissue to create internal stresses in the tissue.

39. The apparatus of claim 38 where the means for changing material parameters of the tissue comprises means for causing a current to flow (see electrode 18 in figures 9 and power source 20 in figure 7) in the tissue.

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40. The apparatus of claim 35 further means for comprising monitoring (324 in figure 27; see col. 18:7-27) the stresses in the tissue and means for controlling (338 in figure 27, 350,329,346) the current flowing in the tissue according to the stresses therein.

41. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring impedance (col. 18:27) of the tissue.

42. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring optical properties (col. 18:8-10) of the tissue.

43. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring pH (col. 18:8-10) of the tissue.

44. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring gas formation (col. 18:8-10) in the tissue.

45. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring acoustic properties (col. 18:8-10) of the tissue.

46. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring color of the tissue as caused by a chemical dye

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(electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) disposed therein.

47. The apparatus of claim 40 where the means for monitoring the stresses in the tissue comprises means for monitoring color (electrochemical, chemical, optical sensors all disclosed in col. 18:7-27) of the tissue as caused by electroplating a material thereon.

48. The apparatus of claim 35 where the means for causing a current to flow in the tissue comprises means for applying a voltage (power source 20) of predetermined ("preset", col. 24:46-59) polarity to obtain a predetermined bioeffect (intended use language). A recitation of the intended use of the claimed invention must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

49. The apparatus of claim 48 where the means for applying a current of predetermined ("preset", col. 24:46-59) polarity to obtain a predetermined bioeffect comprises means for applying voltage pulses (power source 20) of the same polarity to form a DC pulse train (intended use language) A recitation of the intended use of the claimed invention must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

50. The apparatus of claim 49 where the means for applying a voltage of predetermined ("preset", col. 24:46) polarity to obtain a predetermined bioeffect comprises means for applying a first sequence of voltage pulses of the same polarity (power source 20) and means for applying a second sequence (power source 20) of voltage pulses of the opposite polarity (power source 20) to form a complex DC pulse train (intended use language). A recitation of the intended use of the claimed invention must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

51. The apparatus of claim 50 where the means for applying a first sequence (power source 20) and means for applying a second sequence (power source 20) of voltage pulses provide a net charge cancellation when integrated over an application time (intended use language). A recitation of the intended use of the claimed invention must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

52. The apparatus of claim 49 where the means for applying a voltage of predetermined ("preset", col. 24:46) polarity to obtain a predetermined bioeffect comprises means for flowing current from a positive electrode to obtain tissue compression in the proximity of

the positive electrode. This claim includes intended use language. The patent inherently includes tissue compression at the positive electrode. The prior art need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

53. The apparatus of claim 49 where the means for applying a voltage of predetermined ("preset", col. 24:46) polarity to obtain a predetermined bioeffect comprises means for flowing current from a negative electrode to obtain tissue lengthening in the proximity of the negative electrode. This claim includes intended use language. The patent inherently includes tissue lengthening at the negative electrode. The prior art need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

54. The apparatus of claim 35 where the means for creating stress in the tissue comprises creating means for (16,18,20) tension, compression, shear or combinations thereof in the tissue. This claim includes intended use language. The patent inherently includes tissue lengthening at the negative electrode. The prior art need not expressly disclose this characteristic/property (see MPEP § 2112 I, II).

55. The apparatus of claim 35 where the means for causing a current to flow in the tissue comprises means for applying a DC voltage (20) for a predetermined ("preset", col. 24:46) application time across two paired conductive elements (18 in figure 12) in contact with the tissue.



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56. The apparatus of claim 55 where the means for applying a DC voltage for a predetermined ("preset", col. 24:46) application time (350,329,346,338) across two paired conductive elements comprises means for (12 with 16) placing a solid conductive element (18) in contact with the tissue, including solid conductive elements composed of metals or conductive polymers (see col. 15:53-55).

57. The apparatus of claim 55 where the means for applying a DC voltage for a predetermined ("preset", col. 24:46) application time across two paired conductive elements (18 in figure 12) comprises means for placing a conductive gel or solution (58 in figures 23; col. 19:45-61) in contact with the tissue.

58. The apparatus of claim 55 where the means for applying a DC voltage for a predetermined ("preset", col. 24:46) application time (350,329,346,338) across two paired conductive elements comprises means for penetrating the tissue with at least one conductive needle (figure 9f, 18) as providing contact with one of the pair of electrodes.

59. The apparatus of claim 55 where the means for applying a DC voltage for a predetermined ("preset", col. 24:46) application time (350,329,346,338) across two paired conductive elements (18) comprises means for contacting the tissue with an array (figure 12, figures 14-18) of point contacts.

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60. The apparatus of claim 35 where the means for creating stress in the tissue and the means for causing a current to flow in the tissue comprises means for contacting (12 with 16) the tissue with a pair of curved (figure 17, element 18) electrodes.

61. The apparatus of claim 60 where the means for contacting the tissue with a pair of curved electrodes comprises means for contacting the tissue with a sharply angled electrode (figure 11, element 18).

62. The apparatus of claim 60 where the means for contacting the tissue with a pair of curved electrodes comprises means for contacting the tissue with a smoothly angled electrode (figure 12, element 18).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pete Vrettakos  
July 31, 2006



  
ROY D. GIBSON  
PRIMARY EXAMINER